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Why we wrote….*Medicine, Patients and the Law*

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Biographical Information

Margaret Brazier has been a Professor of Law at the University of Manchester since 1990, and she is (with John Harris) joint director of the Centre for Social Ethics and Policy. She has written widely on medical law and ethics, especially on questions of autonomy, reproductive medicine and the human body. She chaired a review of laws relating to surrogacy from 1996 to 1998 and chaired the Retained Organs Commission from 2001 to 2004. From 2004 – 2006 she was chair of the Nuffield Council on Bioethics Working Party on *Critical Decisions in Fetal and Neonatal Medicine*. She is Editor of the *Medical Law Review*. In 2007 she was elected a Fellow of the Academy of Medical Sciences and in 2008 she was appointed Queen's Counsel (*honoris causa*).

Emma Cave graduated in law in 1995 (MJur 1997; PhD 2002) and is a Senior Lecturer at the University of Leeds where she teaches Medical Law, Tort and Jurisprudence. Her research interests include research ethics, and legal and ethical issues in reproductive medicine, and she is author of *The Mother of All Crimes* published in 2004.

Introduction

As befits any self-respecting book on medical law, the 'embryo' *Medicine, Patients and the Law* had a complicated parentage. The book should have had two fathers, Professor Harry Street and Professor Gerald Dworkin, and one mother, Margot Brazier. Sadly, Harry Street died suddenly in 1989. Gerald Dworkin found his many other professional commitments prevented him from co-authoring the work.[1] Thus the first edition of *Medicine, Patients and the Law* was born to a single mother, Margot Brazier, in 1987.[2] The infant survived 20 years of her care (through the second and third editions) until 2007 when Emma Cave took on a co-parenting role for the fourth and current edition.

The law's engagement with medicine has a long history. However, for the first eight years or so of the twentieth century, academic study of medical jurisprudence and

[1] Professor Dworkin kindly provided initial drafts of the chapters on transplantation, defining death and end of life.
[2] A second edition was published in 1992 and a third edition came out in 2003.

litigation involving medicine were nigh on invisible.[3] Nor did UK legislation much concern itself with medical ethics or medical practice.[4] In the universities (at least those south of the Scottish border) medical law as a possible subject of study was unknown. No wonder Kennedy and Grubb declare:

> 'Medical law is still a comparatively young subject.'[5]

By the 1980's change was in the wind. In 1981 Ian Kennedy published his Reith Lectures in *The Unmasking of Medicine*[6] attacking the dominance and paternalism of the medical profession. The courts began to hear more challenges to medical decision-making. Victoria Gillick's attempt to require that any advice or treatment relating to abortion or contraception offered to girls under the age of 16 needed parental consent, generated media publicity and public debate.[7] The prosecution of a distinguished paediatrician Dr Leonard Arthur in 1981 prompted reflection not just on the care of severely disabled babies but about the nature of human life itself.[8] And the Warnock report in 1984 on the regulation of the emergent reproductive technologies offered new vistas for study.[9] To a young lecturer of the day medical law looked both exciting and an area of study that could profoundly affect how we live our lives. It involved a multiplicity of disciplines taking a rather conventional tort lawyer out of the law school to consort with philosophers, theologians and health professionals. Intellectual curiosity, and a sense of being part of a new frontier of knowledge and debate, drove the first edition of the book. In the long hard days of writing the book, a strong desire to complete what Harry Street had started provided stamina.

The book in the beginning

As drafts of the first edition began to take shape, Ken Mason and Sandy McCall Smith published the first edition of their masterly work, *Law and Medical Ethics*[10]. The Edinburgh duo reached the finishing post first. Their success proved a blessing even though it was a blessing that at first seemed well disguised. Given that in 1986 medical law was rarely taught at any level, would the market bear another book? Was there anything to say that Mason and McCall Smith had not said? Medical law cannot be divorced from medical ethics. But writing the first edition of this book, the emphasis became increasingly focused on law, how it worked, what policy considerations determined law's regulation of medicine. As we say in the Introduction to the current edition 'Law matters.' Thus we seek to cover the whole panorama of law's interaction with medical practice and medical progress, with one major exception. *Medicine, Patients and the Law* does not deal with mental health law. This is without doubt a subject in its own right and were we to try to include mental health

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[3] See M. Brazier 'The Age of Deference: A Historical Anomaly?' in MDA Freeman (ed) *Law and Bioethics II* ( ) (forthcoming)*MB to check*

[4] The Human Tissue Act 1961 attracted little attention and the Abortion Act 1967 was seen as primarily a matter of criminal (not medical law).

[5] A. Grubb *Kennedy and Grubb: Medical Law* (3rd ed) (Butterworths, 2000) at p. 3

[6] I. Kennedy *The Unmasking of Medicine*

[7] *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402, HL

[8] *R v Arthur* (1981) 12 BLMR 1

[9] *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984) (Cmnd 9314) (the Warnock Report)

[10] See JK Mason and GT Laurie *Mason and McCall Smith's Law and Medical Ethics* (7th ed) (Oxford University Press, 2006)

law, a book currently comprising 541 pages would double in size. We concentrate on English Law. Back in 1987 case-law in England was relatively sparse. It was still possible to enjoy the luxury of devoting several pages to a single decision of the House of Lords. To answer many questions, resort was needed to precedents from the USA, Australia or Canada. Now we drown in case-law, legislation, new regulations and guidelines. Preparing a new edition is like preparing for a monstrous examination feasible only with the support of colleagues who read drafts and bring new issues to our attention. We are (alas) never fully up to date. Medical law in 2008 is a rapidly moving target.

The book today

The object of the book is to examine the regulation of medical practice, the rights and duties of patients and their medical advisers, the provision of compensation for medical mishaps and the framework of rules governing those delicate issues of life and death where medicine, morals and law overlap. It is intended to provide a picture of the role of law in medical practice today and to highlight those areas where the law is in need of reform.

The book is intended for a wide audience. It is designed to be read by medical students and members of the medical professions, by lawyers and law students seeking an introduction to the law relating to medical practice, and by the lay public, looking for a guide through the maze of current issues confronting them every day in their daily newspaper.

It is divided into three parts. In Part I, we consider the general legal framework within which medicine is practised today. Rarely a day passes without the media focusing on some issue of disputed medical practice, ethics or litigation. The medical profession finds itself in the limelight, often uncomfortably accused of authoritarian and unethical conduct. Part I thus addresses the regulation of medicine in the UK, evaluates human rights and medicine, introduces a discussion of critical medical ethics and concludes with an examination of the core obligation of confidentiality and the difficult questions relating to medical privacy. In the fourth edition we focused on reform of the General Medical Council (GMC) and the more radical reforms proposed by the Shipman Inquiry[11]. Access to health care and debates about rights to health care are considered in the light of both structural changes within the NHS and relevant domestic and EU cases. In Chapter 4, the continuing stream of cases on rights to privacy is examined together with the growing focus on and concern about genetic privacy.

In Part II, we look at legal remedies available to the patient injured by, or unhappy with, treatment he or she has received. Informed consent remains a major legal and ethical dilemma and the fourth edition examines the seminal case of *Chester v Afshar*[12] in the context of both patient autonomy and the willingness of the judiciary to modify principle in the interests of policy and justice. The Mental Capacity Act 2005 is fully addressed in a chapter on competence, consent and compulsion. Through the book we concentrate, primarily, on the provision of health care for the mentally

[11] See *Safeguarding Patients: Lessons from the Past – Proposals for the Future*, Cm 6394 (DH, 2004).
[12] [2004] UKHL 41.

competent patient. In Chapter 5, we do address the problems arising when a patient is temporarily or permanently mentally incapacitated. While we leave mental health law as such to others, no discussion of consent can avoid the crucial questions of capacity. The number of actions for malpractice against doctors, once virtually unknown in England, has grown apace. Doctors fear an epidemic of US proportions. Patients find the English legal system obstructive and cripplingly expensive. Nor are their grievances limited to the lack of provision for compensation for medical mishap. Increasingly patients demand a greater say in their treatment. The extent to which it is right for patients to have their say becomes ultimately a question for the law.

In an attempt to foster confidence in the NHS, the Department of Health implemented a series of reforms to increase patient choice and provide suitable redress when things go wrong. A new complaints procedure was put into practice in 2004[13] with the formation of the Independent Complaints Advocacy Service. A three year plan to improve patient access to both general and personalised information was announced in December 2004 and, in May 2005, reforms to cut waiting time and replace waiting lists by a booked appointment system were announced. The Chief Medical Officer's report on clinical negligence *Making Amends*[14] has led to the proposal of a new NHS Redress Scheme to speed up explanation, compensation and apology. A watered down version of those proposals is now contained in the NHS Redress Act 2006 which is considered in Chapter 9.

In Part III, we examine in detail specific issues relating to the treatment of the living and the dying which have posed awkward problems of law, morals and medicine. Medical progress fuels legal and ethical debate. Whilst it has enabled the extension of life at one end of the spectrum, it has brought new hope to the childless at the other. The Human Fertilisation and Embryology Bill is considered. Questions of family status following fertility treatment and gamete donation have caused legal battles. Pre-implantation genetic diagnosis and tissue typing resulted in the Law Lords addressing the thorny problem of saviour siblings.[15] Definitions of the beginning of life beg questions about the appropriateness of research on embryos, abortion and the treatment of the damaged newborn baby. New Regulations[16] attempt to facilitate international research and enhance ethical protection of participants, but they come at a price. Bureaucracy and complex legal rules continue to baffle researchers and ethics committees. Cloning opens up yet more difficult questions about the nature of human life. Meanwhile at the end of life, the fate of disabled neonates troubled the courts once more, most poignantly in *Re Wyatt*.[17] The implications of *Burke*[18] are unravelled and Lord Joffe's Assisted Dying Bills[19] examined. The Human Tissue Act 2004 is addressed.

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[13] NHS (Complaints) Regulations 2004.
[14] Chief Medical Officer, *Making Amends – Clinical Negligence Reform*, (DH, 2003).
[15] R *(on the application of Quintavalle v Human Fertilisation and Embryology Authority* [2005] 2 All ER 555, H.L
[16] Medicines for Human Use (Clinical Trials) Regulations 2004.
[17] *Re Wyatt* [2004] EWHC 2247; [2005] EWHC 117; [2005] EWHC 693; [2005] EWHC 2902; [2006] EWHC 319; *Wyatt v Portmouth NHS Trust* [2005] EWCA Civ 1181.
[18] *R. (On the application of Burke) v General Medical Council* [2004] EWHC 1879 (Admin); *R (On the application of Burke) v General Medical Council* [2005] EWCA Civ. 1003; *Burke v United Kingdom* [2006] App. 19807/06.
[19] See Select Committee on the Assisted Dying for the Terminally Ill Bill, *HL Paper 86* (2005),

Emma joins 'The Team'

The third edition of the book came out in 2003. A fourth edition was soon pressing. The growth of medical law made the prospect of writing a book covering the whole of this area daunting, albeit others have done it with great success. So a co-author was sorely needed. For Margot the key questions were: who could I write with effectively without too much conflict on ideas, who could bring new vision to the book, and who could put up with me? Collaboration in academic life can be hugely rewarding but not always easy. The book was very much 'my baby'. So when Emma Cave said yes to my invitation the sense of relief was great.

Emma writes

Two emotions prevailed when Margot invited me to co-author the fourth edition of *Medicine, Patients and the Law*. Gratitude was followed closely by sheer terror. The first sentiment is easy to appreciate. *Medicine, Patients and the Law* was already established as a leading text book in the field. Reviews were excellent. On a personal level I was excited to broaden my horizons and look at new areas within medical law with increased scrutiny. More importantly, I would get to work with Margot again.

Margot was on the interview panel which gave me my first job: a Research Assistant on an NHS sponsored study to design and deliver training for research ethics committees. I was based at the Centre for Professional Ethics at the University of Central Lancashire and worked closely with Margot at the University of Manchester. Her name appeared beside mine in one of my first published articles.[20] My next research post was at the Institute for Medicine, Law and Bioethics at the University Manchester before I became a Lecturer at Leeds. We knew that we could work together. Margot has long been my inspiration to pursue a career in Medical Law and I was delighted to work with her again. Given the above, the second emotion is also easy to understand. How was I to emulate Margot's style, use of examples and legal knowledge?

The School of Law at Leeds was hugely supportive. I had just returned from maternity leave, but they recognised the value in this amazing opportunity and awarded me study leave. Margot and I duly split the chapters and half were rather inappropriately labelled 'mine'. Drafts flew back and forth across the Pennines and so began the redrafting of those sections that required it. The law had changed dramatically since 2003 and some chapters required extensive rewriting. We made significant changes to all. Margot was entirely open to suggestions for change in a way I could not have been if an impostor dared to tamper with a creation of mine. I am hugely indebted to her, not only for inviting me to co-author the book, but for making it such fun.

Sometimes we both had to reflect carefully on our own views especially on ethical questions. We do not wholly agree on the ethics of abortion or the moral status of the fetus. But such reflection sharpened our focus on what the law should do in areas of

[20] M. Brazier, E. Pickworth, 'Fees and Research Ethics Committees' *Bulletin of Medical Ethics*, 151:1999,18.

moral controversy. Some sections were difficult to write. Convoluted laws, such as those governing the regulation of doctors, as well as attempts to simplify law (in particular the National Health Service Act 2006) presented challenges in relation to their presentation. The most difficult of 'my' (Emma's) chapters were paradoxically the most rewarding to write. We aimed to make the book accessible to a broad audience and so included in Chapter 1 a section on the General Medical Council which many text books omit largely due to the incredible pace of (ongoing) reform in recent years. Similarly, a new Chapter 9 on complaints and redress addressed new complaints procedures and the NHS Redress Act 2006. The area I knew most about when embarking on the co-authorship was medical research, but this chapter took a good deal of time to re-work. The Medicines for Human Use (Clinical Trials) Regulations 2004 are, at times, as dry as they sound, though the ethical quandaries they address continue to present challenges.

What next?

Brief freedom from slaving over a new edition has provided an opportunity for reflection. In this paper we have referred to *medical* law, but should we in the twenty-first century refer rather to health care law or health law? In our title, *Medicine, Patients and the Law* we try to avoid this nagging controversy, but there is no doubt we focus on doctors rather than other health professionals. Our efforts to limit the length of the book so as to ensure readability are proving increasingly difficult to accomplish. A companion book focusing on nursing, patients and the law[21] is an increasingly attractive proposal, and one that while we might not undertake it ourselves we would love to act as midwife to! Constraints of space make it difficult to accommodate some increasingly important areas of law. Public health and genetics are just two examples.

But we need to reflect on more than content. Twenty one years on we have to revisit the objectives of the book. Whilst we aim to do more than describe the law, the incorporation of two sometimes varying views on controversial issues helps us to guard against overly polemical discourse. We have taken time to absorb the ever growing numbers of books and articles about this subject that we love. In the 21 years since the first edition of our book the community of scholars researching medical law and ethics has expanded immensely, specialist journals have emerged, and the study of medical law has become hugely popular at undergraduate and postgraduate levels.

In the year since the last edition of *Medicine, Patients and the Law* was published, Parliament has been busy. The Health and Social Care Act 2008 reforms professional regulation and introduces yet another new regulator, the Care Quality Commission. The Corporate Manslaughter and Corporate Homicide Act 2007 could have far reaching implications for NHS Trusts in so far as it creates an offence by which an organisation that causes death by gross negligence can be prosecuted. For example, in cases when patients die from hospital acquired infections there may be no individual to single out for blame and stand in the dock. Trusts may now face criminal liability for gross failures in their systems of patient care. By the time a draft of a new edition

[21] See, for example, N. Fletcher ,J.Holt, M.Brazier and J..Harris *Ethics, Law and Nursing* (Manchester University Press,1995) now sadly very out of date.

is complete we assume that the new Human Fertilisation and Embryology Bill will have made its controversial and tortuous way to the statute book. The Human Tissue Act 2004, despite being in force a mere two years, may be changed again as pressure grows to address transplant waiting lists and the Prime Minister appeared to throw his weight behind a move to presumed consent. Case law is harder to predict but we already know that a series of challenges to decisions about provision of cancer drugs will perpetuate a focus on the postcode lottery. Increasingly the impact of the Human Rights Convention must be fully assessed. Article 8 of the European Convention on Human Rights continues its transformation of the action for breach of confidence into something that, while it does not bear the name of privacy, seems a million miles away from older versions of breach of confidence. In *R v (Axon) v Secretary of State for Health*[22] it was confirmed that mature minors have a right to confidentiality even against their parents, albeit they still have no right to veto treatment. The seminal case of *Gillick* was confirmed post Human Rights Act 1998. A number of patients have challenged the judgments of the English courts in the European Court of Human Rights in Strasbourg. In the most notable of those cases, the United Kingdom was held to have breached Article 8 in refusing to exercise its discretion to allow a prisoner to obtain artificial insemination facilities in *Dickson v UK*.[23] Article 8 begins to sow the seeds of at least some sort of right to procreate. But the judgment in *Dickson* is complex and we sense that English lawyers need to become much more familiar with the intricacies of the jurisprudence of the Strasbourg court.

New legislation and case law, and academic commentary are challenges that anyone writing a critical legal text must face. We cannot claim any exemption from that burden. Harder perhaps is the need to try to stay ahead of the judges and the legislators. Developments in medical science pose novel legal and ethical questions and we have to try to suggest some possible answers, whilst sometimes struggling to understand the science itself. So we are fortunate in having a marvellous 'back stage' team of friends and relatives to put us right on both science and the reality of health care practice and look forward to engaging them again when we start on the 5th edition. Consider the possible 'new' dilemmas the law may have to address. If womb transplants become feasible, could a man demand a womb? If artificial wombs show promise in animal trials, how would ectogenesis be regulated? All too quickly in our field, science fiction becomes fact.

[22] [2006] EWHC 37.
[23] [2007] Application No.: 00044362/04.